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February 11, 2003

via E-mail to: SAPcomments@cdc.gov

Minh Thomas
Management and Program Analyst
Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Rd., MS E-79
Atlanta, GA 30333

Re: Comments on Center for Disease Control and Prevention, Office of Inspector General, Department of Health and Human Service 42 CFR Part 73 and 1003, Possession, Use, and Transfer of Select Agents and Toxins: Interim Final Rule, December 13, 2002.

Dear Ms. Thomas:

Elan Pharmaceuticals, Inc. ("Elan") appreciates this opportunity to comment on the Centers for Disease Control and Prevention, Office of Inspector General, Department of Heath and Human Services interim final rule regarding the possession, use, and transfer of select agents and toxins published in 67 Fed. Reg. 76886 on December 13, 2002 ("Interim Final Rule").

Elan is focused on the discovery, development, manufacturing, selling, and marketing of novel therapeutic products in neurology, pain management, and autoimmune diseases. We understand the implementation of the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 will provide protection against misuse of select agents and toxins.

In addition, we appreciate that the Interim Rule exempts, 1) products cleared, approved, licensed, or registered under certain laws–§73.6(b), including the Federal Food, Drug, and Cosmetic Act, Section 351 of the Public Health Service Act pertaining to biological products, the Virus-Serum-Toxin Act, and the Federal Insecticide, Fungicide and Rodenticide Act; and 2) investigational products on a case-by-case basis –§73.6(c), when the study being conducted is authorized under –§73.6(b).

Considering these exemptions, Elan offers the following comments:

1. **Exemption for Commercial Products Require Further Definition –§73.6(b)(1)**

   Both in-process and final product commercial product materials intended for therapeutic application, including those materials required to support commercial products but not necessarily placed into commercial distribution (e.g., product stability materials, product samples), and which are orders of magnitude below the lethal limits, should be exempt in accordance with –§73.6(b)(1).

2. **Exemption for Investigational Drugs Require Further Definition –§73.6(c)**

   Both in-process and final product clinical research materials intended for therapeutic application, including those materials required to support clinical studies but not necessarily used as part of clinical studies (e.g., product stability materials), and which are orders of magnitude below the lethal limits, should be exempt in accordance with –§73.6 (b).

3. **Security Risk Assessment Attorney General Specify Review Times –§73.8**

   To allow for unencumbered research, development, and manufacturing of products covered under – §73.6(b), this process should be further defined, specifically as to the length of time it will take the Attorney General to conduct the risk assessment for entities and individuals.

4. **Transfers, CDC Authorization –§73.14 (d)**

   Per 73.14 (a)(b), any recipient of a select agent transfer must have a certificate of registration and therefore must have CDC pre-approval. Therefore, sub-part 73.14(d) requires clarification in that it stipulates that CDC must authorize all transfers prior to shipment. Shipments between registered sites are part of daily business operations during clinical and commercial manufacturing, and therefore this pre-authorization should be further defined or exempted for such shipments.

5. **Records, Phased Implementation –§73.15**

   New records requirements –§73.15, need to have a phased implementation similar to the new security–§73.1 and new training –§73.13 requirements. There is a relationship between several sections of the new records and new security requirements and implementation of these parts of the Interim Final Rule need to be coordinated along the similar phased implementation.

6. **Non-Availability of Application Package and Forms**

   As of February 11, 2003, the application package and forms are not available on the CDC website (CDC links http://www.cdc.gov/od/sap/downloads2.htm and http://www.cdc.gov/od/sap/addforms.htm). We request immediate availability of these documents to avoid unnecessary difficulties in meeting the March 12, 2003 deadline for registration of an entity and Responsible Official.

Elan appreciates your consideration of these comments and looks forward to further discussion on the important issues raised and implementation of the rule. If you have any questions or need more information regarding our comments, please feel free to contact me, tel. 650-877-7468 or, e-mail, andrew.grethlein@elan.com

Respectfully submitted by,

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